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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,088	07/13/2001	Konstantin Petrukhin	20267P	3787

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EXAMINER
RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
1652	11

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,088	PETRUKHIN ET AL.	
	Examin r	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *10 and 12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-15 are still at issue and are present for examination. Claims 1-9 and 11 are now under consideration. Claims 10, 12-15 have been withdrawn from consideration as being drawn to non-elected invention.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-9 and 11 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that coexamination of all of Groups I-IV would not require independent searches. This is not found persuasive because while the searches for the groups may overlap, they are not coextensive. The search for Groups II-IV would each require the search of subclasses unnecessary for the search of elected Group I. For example, search of Group I would require search of class/subclass 435/182 and class 536/23.2 while search of Group III would require search of subclass 530/387.9. For applicants convenience, Examiner has already included the DNA and the polypeptides in a single group, Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10, 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9.

Claim Objections

Claim 6 is objected to because of the following informalities: Claim 6 recites an

abbreviation "CYB5RP". Examiner requests that applicants provide the expansion for the above abbreviation at least wherever it occurs first Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 3 is directed to a "DNA molecule" which reads on the product of nature. Amending the claim to read as "AN isolated DNA molecule..." to show the hand of man would overcome the above rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the phrase "under stringent conditions". It is not clear to the Examiner as to what applicants amen by the above phrase. The specification provides a definition for "high stringency condition", however, the metes and bounds of the phrase "stringent conditions" are not clear to the Examiner.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is directed to a "CYB5RP protein". Even though the specification indicates that the above protein has a delta-6 fatty acid desaturase activity, it is unclear to the Examiner as to whether applicants are claiming a CYB5RP with a desaturase activity since applicants do not explicitly include such activity in the claim. Therefore, for purposes of examination Examiner takes the position that applicant shave claimed a cytochrome B5 related protein which may or may not have the desaturase function.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "amino acid substitutions" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is directed to "amino acid substitutions" (plural). It is not clear whether applicants are claiming multiple substitutions or a single substitution as in claim 7 rendering the claim indefinite. It appears that claim 9 should depend from claim 7 which is drawn to a protein of claim 6 containing a single amino acid substitution (singular). If so, amending the claim accordingly would overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA with SEQ ID NO:1, 2 or DNA with SEQ ID NO:2 lacking positions 1,019-1,054; positions 71-1405 of SEQ ID NO:2 or positions 71-1405 of SEQ ID NO:2 lacking positions 1,019-1,054 encoding a polypeptide having a delta 6-fatty acid desaturase activity and an amino acid sequence SEQ ID NO:3 or amino acid sequence SEQ ID NO:3 lacking amino acid positions 317-328, does not reasonably provide enablement for any DNA molecule which hybridizes to any of the above polynucleotides under any stringent conditions including variants, mutants recombinants and fragments or any DNA or RNA oligonucleotide comprising at least 18 contiguous nucleotides of at least one of the above polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 3 and 11 are so broad as to encompass any DNA from any source, irrespective of the fact whether it encodes the polypeptide with SEQ ID NO:3 having the delta 6 desaturase

activity but which can hybridize to the above polynucleotides under any stringent conditions. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA sequences that are broadly encompassed by the claims.

The applicants propose to use the above polynucleotides for a variety of processes such as recombinant protein preparation, as hybridization probes, for identification of mRNA or for isolation of genomic clones. Applicants also propose to use the DNA sequences in the form of oligonucleotide probes. Since the nucleotide sequence determines the type of protein and the ultimate function of the encoded protein and since only nucleic acids with very high percent homology can be used as a probe for either identifying mRNA or for screening a cDNA library, changing the nucleotide sequences as proposed by the applicants and/or addition of substantial amount of additional nucleotide sequence *unrelated* to the nucleic acid sequences described in the first paragraph above may not lead to desired function of the polynucleotides. This is because the changes suggested by the applicants will result in an enormous number of nucleotide sequences that will hybridize to several unrelated mRNAs instead of hybridizing specifically to the mRNA of interest and similarly may hybridize to cDNAs totally unrelated to the cDNAS of interest while screening a cDNA library. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of a single delta-6 fatty acid desaturase from humans.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or modifications of nucleotides, as encompassed by the instant claims, and the base changes within a nucleic acid's sequence can be made with a reasonable

expectation of success in obtaining the desired activity/utility are limited and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given DNA to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA comprising 18 contiguous nucleotides capable of hybridizing to the above polynucleotides (irrespective of its capability of encoding an amino acid with SEQ ID NO:3) because the specification does not establish: (A) regions of the DNA sequence which may be modified without effecting the above mentioned activity/utility; (B) the general tolerance of delta-6 fatty acid desaturase DNA sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any delta 6 fatty acid desaturase encoding nucleotide sequence with an expectation of obtaining the desired biological function and utility; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA fragment of a polynucleotide simply comprising 18 contiguous nucleotides of the above polynucleotides or any DNA fragment which can hybridize to the above polynucleotides under any type of stringent hybridization conditions. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 3 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules which hybridize to the polynucleotides with SEQ ID NO:1 or 2 or those disclosed in claim 2 and polynucleotides comprising 18 contiguous nucleotides of the above polynucleotides.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed by the above claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6-9 are directed to cytochrome b5 **related** proteins with amino acid substitutions essentially mutants or variants of SEQ ID NO:3. Claims 6-9 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:3 including modified polypeptide sequences, modified by at least one substitution of an amino acid residue in SEQ ID NO:3 that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:3 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the function of all the polypeptide sequences derived from SEQ ID NO:3, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions and with the potentiality of generating many different antibodies. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written

description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Petrukhin et al. (Nature genetics, July 1998, Vol. 19:241-247 and GenBank Accession No. AF139813). This rejection is based upon the public availability of a printed publication. Claims 1-5 and 11 of the instant application are drawn to a recombinant polynucleotide encoding the polypeptide with SEQ ID NO:3 or a polynucleotide with either SEQ ID NO:1 or 2 or SEQ ID NO:2 lacking nucleotides 1,019-1,054 or SEQ ID NO:2, positions 71-1405 or positions 71-1405 lacking positions 1,019-1,054, vectors and host cells comprising such polynucleotides. Petrukhin et al. disclose the polynucleotide with SEQ ID NO :1, a vector and a host cell comprising the same. Petrukhin et al. disclose a 1.4 Mb DNA contig comprising the polynucleotide with SEQ ID NO:1 (see enclosed three segment (positions 1-600, positions 9000-9500 and 18,000-18,401) sequence match) anticipating claims 1-5 and 11. Thus Petrukhin et al. anticipate claims 1-5 and 11 of this application as written.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao
November 26, 2002